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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,718	03/21/2001	Paul Schimmel	TSRI 817.0	3346

7590 01/12/2004

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EXAMINER	
NICKOL, GARY B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/813,718	SCHIMMEL ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,5,7,8,36 and 49-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,5,7,8,36 and 49-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Amendment

Re: Schimmel *et al.*

Date of priority: March 21, 2001

The Amendment filed October 29, 2003 in response to the Office Action of July 29, 2003 is acknowledged and has been entered.

Claims 3, 5, 7-8, 36, and 49-51 are pending and are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

New Rejections:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3, 5, 7-8, 36, and 49-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Schimmel *et al.* (US 2003/0017564 A1, February 23, 2001)

The applied reference has two common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Schimmel *et al.* teach an isolated truncated tryptophanyl-tRNA synthetase polypeptide comprising a Rossman fold nucleotide binding domain, wherein the isolated polypeptide is capable of regulating vascular endothelial cell function (angiostatic- see page 14, Example 3) and has a size of at least about 46 kilodaltons and less than full length tryptophanyl-tRNA synthetase having a size of about 54 kilodaltons wherein the polypeptide is human (paragraph 0151). Schimmel *et al.* further teach that the isolated polypeptide has amino-terminal truncation (paragraph 15) and that the polypeptide of the present invention can also be utilized in combination with a suitable pharmaceutical carrier. Such compositions comprise a therapeutically effective amount of the protein, and a pharmaceutically acceptable carrier or excipient (paragraph 129). Schimmel *et al.* further teach that the truncated tryptophanyl-tRNA synthetase polypeptide comprises amino acid residues 48-471 of SEQ ID NO:10 or amino acid residues 71-471 of SEQ ID NO:10. For example, see Schimmel's disclosure of SEQ ID NO:3 on page 21.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 5, 7-8, 49-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Tolstrup *et al.* (Jnl. Biol.Chem. Vol. 270, No. 1 January 1995, IDS).

Tolstrup *et al.* teach a human truncated tryptophanyl-tRNA synthetase polypeptide that comprises 424 amino acids that is approximately 48.2 kDa (page 401, 1st column, 2nd paragraph) that is generated by the deletion of the amino terminal domain through alternative splicing of the pre-mRNA. Also, see the Schimmel *et al.* reference **above**, specifically, page 1, paragraph 6, line 9 wherein Tolstrup *et al.* is specifically referenced to teach mini TrpRS. Absent evidence to the contrary, this is the same polypeptide as claimed and comprises amino acid residues 48-471 of SEQ ID NO:10 or amino acid residues 71-471 of SEQ ID NO:10 wherein it is further noted that amino acid residues 48-471 of SEQ ID NO:10 comprise a 424 amino acid polypeptide. Lastly, although the prior art does not teach that the polypeptide of Tolstrup *et al.* is produced by cleavage of the polypeptide of SEQ ID NO:10 with PMN leucocyte elastase, the product of the prior art appears to be the same as that which is claimed. ("Approximately" is a subjective term that that does not necessarily limit the molecular weight of the claimed polypeptide. One of ordinary skill in the art could reasonably conclude that at 48.2 kDA, the polypeptide of Tolstrup's approximates a polypeptide this is also around 47 kDa.) The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claims 3, 5, 7, 8, 36, 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Cong *et al.* (WO 99/13075-A2, March 1999).

Cong *et al.* teach an isolated human polypeptide comprising 471 amino acids that is 99.1% identical to amino acids 48-471 of SEQ ID NO:10 as disclosed by dependent Claim 49 and amino acids 71-471 of SEQ ID NO:10 as disclosed by dependent Claim 50. (see attached sequence listing). Further, at 471 amino acids, the polypeptide of Cong *et al.* has less amino acids than **full-length** tryptophanyl-tRNA synthetase which is approximately 184 amino acids long. Hence, it appears that the polypeptide of Cong *et al.* is an isolated truncated tryptophanyl-tRNA synthetase polypeptide that has a size of at least about 46 kilodaltons and less than a size of about 54 kilodaltons. Further, since there is a high degree of amino acid similarity between SEQ ID NO:10 and the polypeptide of Cong *et al.*, it would appear that the functional limitations of the claimed polypeptide are inherently disclosed by Cong *et al.* Lastly, although the prior art does not teach that the polypeptide of Cong *et al.* is around 47 kD produced by cleavage of the polypeptide of SEQ ID NO:10 with PMN leucocyte elastase, the product of the prior art appears to be the same as that which is claimed. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See

In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 7, 8, and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth an isolated truncated tryptophanyl-tRNA synthetase polypeptide comprising a Rossman fold nucleotide binding domain, wherein the isolated polypeptide *inhibits vascular endothelial cell proliferation* and has a size of at least about 46 kilodaltons and less than full length tryptophanyl-tRNA synthetase having a size of about 54 kilodaltons. Thus, the written description is not commensurate in scope with the claims drawn to a genus of truncated polypeptides capable of regulating vascular endothelial cell function.

The specification teaches that truncated tRNA synthetase polypeptides are polypeptides that are shorter than the corresponding full length tRNA synthetase. The specification further teaches that the invention encompasses fragments, derivatives or analogs of the polypeptide of

SEQ ID NO:10 in which one or more of the amino acid residues are substituted with a conserved or non-conserved amino acid residue. Thus, the claimed polypeptides encompass a genus of polypeptide fragments. And, although the claims provide some information regarding the chemical structure and function of the claimed genus, said information is insufficient because the alleged functional activity is generic and does not represent a "specific activity" of the genus. See example 9 of the written description guidelines at http://www.uspto.gov/web/menu/written Although the example is drawn to hybridizing claims, the example illustrates the need to disclose a specific functional activity commensurate in scope with the claimed genus. Hence, a polypeptide that is capable of regulating vascular endothelial cell function is not a specific function activity representative of the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of antagonists, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required.

See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated truncated tryptophanyl-tRNA synthetase polypeptide comprising a Rossman fold nucleotide binding domain, wherein the isolated polypeptide *inhibits vascular endothelial cell proliferation* and has a size of at least about 46 kilodaltons and less than full length tryptophanyl-tRNA synthetase having a size of about 54 kilodaltons, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
January 8, 2004